



Robert Greene Sterne Jorge A. Goldstein David K.S. Cornwell Robert W. Esmond Tracy-Gene G. Durkin Mitchele A. Cimbala Mitchael B. Ray Robert E. Sokohl Eric K. Steffe Mitchael Q. Lee Steven R. Ludwig John M. Covert Linda E. Horner Robert C. Millonig Donald J. Featherstone Timothy J. Shea, Jr Michael V. Messinger Judith U. Kim Patrick E. Garrett
Jeffrey T. Helvey
Heidi L. Kraus
Eldora L. Ellison
Thomas C. Fiala
Donald R. Banowit
Petre A. Jackman
Jeffrey S. Weaver
Brian J. Del Buono
Vingil Lee Beaston
Theodore A. Wood
Elizabeth J. Haanes
Joseph S. Ostroff
Frank R. Cottingham
Rae Lynn P. Guest
Daniel A. Klein
Jason D. Eisenberg

Michael D. Specht Tracy L. Muller Jon E. Wright LuAnne M. DeSantis Ann E. Summerfield Helene C. Carlson Cynthia M. Bouchez Timothy A. Doyle Gaby L. Longsworth Lori A. Gordon Ted J. Ebersole Laura A. Vogel Bryan S. Wade Bashir M.S. Ali Shannon A. Carroll Matthew E. Kelley Michelle K. Holoubekt Marsha A. Rose* W. Blake Coblentz James J. Pohl* John T. Haran* Mark W. Rygiel <u>Registered Patent</u>, Karen R. Markowit Matthew J. Dowd Katrina Yujian Pei

Registered Patent Agents*
Karen R. Markowicz
Marthew J. Dowd
Katina Yujian Pei Quach
Bryan L. Skelton
Robert A. Schwartzman
Teresa A. Colella
Victoria S. Rutherford
Simon J. Elliott
Julie A. Heider
Mita Mukherjee
Scott M. Woodhouse
Christopher J. Walsh

Liliana Di Nola-Bar Peter A-Socarras Jeffrey Milk Danielle L. Letting Lori Brandes

Of Counsel Edward J. Kessler Kenneth C. Bass III Marvin C. Guthrie

*Admitted only in Maryland

*Admitted only in Virginia

*Practice Limited to
Federal Agencies

February 21, 2006

WRITER'S DIRECT NUMBER: (202) 772-8606 INTERNET ADDRESS: ANNS@SKGF.COM

Mail Stop: Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/698,928; Filed: October 31, 2003 For: Novel Cytarabine Monophosphate Prodrugs

Inventors:

Boyer et al.

Our Ref:

2358.0180002/RWE/AES

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover Information Disclosure Statement Filing fee (37 C.F.R. § 1.17(p));
- 2. Second Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(c);
- 3. Two (2) pages of Form PTO/SB/08B citing eleven (11) documents (Documents JI-JS);
- 4. Copies of the eleven (11) cited documents; and
- 5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents February 21, 2006 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

aun & Summefild

Ann E. Summerfield Attorney for Applicants Registration No. 47,982

RWE/AES:law Enclosures

499211_1.DOC



UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BOYER et al.

Appl. No.: 10/698,928

Filed: October 31, 2003

For: Novel Cytarabine Monophosphate

Prodrugs

Confirmation No.: 2990

Art Unit: 1626

Examiner: T. Solola

Atty. Docket: 2358.0180002/RWE/AES

Second Supplemental Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(c)

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed on January 18, 2006 in connection with the captioned application. Copies of all documents cited on accompanying Form PTO/SB/08B, documents JI-JS, are submitted herewith.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier or later than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS

02/23/2006 HALI11

00000100 10698928

01 FC:1806

180.00 OP

Forms based on information presently available to the undersigned. However, the listed

publication dates should not be construed as an admission that the information was

actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention

over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the

teachings purportedly offered.

This statement should not be construed as a representation that a search has been

made, or that information more material to the examination of the present patent

application does not exist. The Examiner is specifically requested not to rely solely on

the material submitted herewith.

This Second Supplemental Information Disclosure Statement is being filed more

than three months after the U.S. filing date AND after the mailing date of the first Office

Action on the merits, but before the mailing date of a Final Rejection, or Notice of

Allowance, or an action that otherwise closes prosecution in the application. Attached is

our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the

fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return copies of the

enclosed IDS Forms, and indicate in the official file wrapper of this patent application

that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Ann E. Summerfield Attorney for Applicants Registration No. 47,982

Date: February 21, >006

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

499163_1.DOC

PTO/SB/08B (07-05)

Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE cond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Co	Complete if Known		
OF COM	o crippi		INITE A T	Application Number	10/698,928		
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	October 31, 2003		
				First Named Inventor	Serge Boyer		
STATEMENT BY APPLICANT				Art Unit	1626		
(Use as many sheets as necessary)			s necessary)	Examiner Name	Solola, Taofiq A.		
Sheet	1	of	2	Attorney Docket Number	2358.0180002/RWE/AES		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T ²
	JI	BRAESS, J. et al. "Oral Cytarabine Octosfate in Acute Myeloid Leukemia and non-Hodgkin's Lymphoma – Phase I/II Studies and Pharmacokietics", <i>Leukemia</i> 12:1618-1626, Stockton Press (1998)	
	IJ	CHABNER, B.A., "Cytidine Analogues", in Cancer Chemotherapy: Principles and Practice, Lippincott Williams & Wilkins (April 1990)	
	JK	CHABNER, B.A., et al., "Purification and Properties of Cytidine Deaminase from Normal and Leukemic Granulocytes", <i>Journal of Clinical Investigation</i> 53:922-931, American Society for Clinical Investigation (March 1974)	
	JL	COHEN, S.S. "The Mechanisms of Lethal Action of Arabinosyl Cytosine (araC) and Arabinosyl Adenine (araA)", Cancer 40:509-518, Wiley (1977)	
	JM	GRANT, S., "Biochemical Modulation of Cytosine Arabinoside", <i>Pharmac. Ther.</i> 48:29-44, Pergamon Press plc (1990)	
	JN	LEACH, W.B. et al. "Toxicity Studies in Mice Treated with 1-ß-D-Arabinofuranosyl-cytosine (ara-C)", Cancer Research 29:529-535, America Association for Cancer Research (March 1969)	
	JO	PLUNKETT, W. et al. "Pharmacologically Directed Ara-C Therapy for Refractory Leukemia", Seminars in Oncology 12(2) Supp. 3:20-30, W.B. Saunders (June 1985)	
	JP	RUSTUM, Y.M., et al. "1-ß-Arabinofuranosylcytosine in Therapy of Leukemia: Preclinical and Clinical Overview" <i>Pharmac. Ther.</i> 56:307-321, Pergamon Press Ltd. (1992)	
	1Ø	SHIMMA, N. et al., "The Design and Synthesis of a New Tumor-Selective Fluoropyrimidine Carbamate, Capecitabine" Bioorganic & Medicinal Chemistry 8:1697-1706, Elsevier Science Ltd. (2000)	
	JR	SUTO, T. et al. "The Effect of YNK-01 (an Oral Prodrug of Cytarabine) on Hepatocellular Carcinoma" Seminars in Oncology 24(2) Suppl 6:S6-122-S6-129, W.B. Saunders (April 1997)	

Examiner Signature	Date Considered	
Signature	Constant	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE cond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO			ari.	Con	Complete if Known		
CE CONE C	TIDEL	TO B 4 TO	INTERNATION	Application Number	10/698,928		
SECOND SUPPLEMENTAL				Filing Date	October 31, 2003		
INFORMA				First Named Inventor	Serge Boyer		
STATEME				Art Unit	1626		
(Use as many sheets as necessary)				Examiner Name	Solola, Taofiq A.		
Sheet	2	of	2	Attorney Docket Number	2358.0180002/RWE/AES		

		NON PATENT LITERATURE DOCUMENTS	٠.
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	JS	YOSHIDA, Y. et al., "Participation of the Peroxisomal ß-Oxidation System in the Chain- Shortening of PCA ₁₆ , A Metabolite of the Cytosine Arabinoside Prodrug, YNK01, in Rat Liver" <i>Biochemical Pharmacology</i> 39(10):1505-1512, Pergamon Press plc (1990)	
		•	

499131.1

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.